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Supreme Court, U.S.
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IN THE
Supreme Court of the United States

AMERICAN TRUCKING ASSOCIATIONS, INC., ET AL.,

Cross-Petitioners,

v.

CAROL M. BROWNER, ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY, ET AL.,

Cross-Respondents.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF THE GENERAL ELECTRIC COMPANY AS AMICUS CURIAE IN SUPPORT OF CROSS-PETITIONERS

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QUESTION PRESENTED

Whether the Environmental Protection Agency is required, in setting nationwide air-quality standards under Section 109 of the Clean Air Act, to consider costs and risk trade-offs in order to engage in reasoned decisionmaking.

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INTEREST OF AMICUS CURIAE

The General Electric Company ("GE") is a diversified manufacturing and financial services company headquartered in Fairfield, Connecticut.[1] GE has numerous business units that provide a broad range of goods and services throughout the United States and the world, including aircraft engines, appliances, capital services, industrial systems, lighting, medical systems, the NBC television network, plastics, power systems, and transportation systems.

GE has a continuing interest in the proper interpretation not only of the Clean Air Act, but of health and safety regulation generally. Society's interests are best served by a rational system of risk management that considers not merely the benefits of proposed agency action, but also costs of compliance and likely risk trade-offs. Because of the diversity of GE's business activities, it can offer helpful guidance to this Court on the need to focus on a global, reasoned, and systematic approach to risk regulation, which will result in better policies that provide more protection for human health and the environment.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case presents an important opportunity not only to correct the Court of Appeals' misinterpretation of Section 109 of the Clean Air Act, but also to establish a broader principle about risk regulation generally. This Court should hold that agency action under environmental and other regulatory statutes, including the Clean Air Act, is not reasoned unless the agency considers (1) costs of compliance (including marginal costs) and (2) risk trade-offs caused by the agency action. The agency must also give a reasoned explanation of how it considered those

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[1] Pursuant to Rule 37.6 of the Rules of this Court, amicus states that no counsel for a party authored this brief in whole or in part, and that no person or entity other than amicus, its members, or its counsel, has made any monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3, amicus states that the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of this Court.

factors. These principles are grounded both in organic regulatory statutes (such as the Clean Air Act) and in the requirements of the Administrative Procedure Act, 5 U.S.C. § 706. *See Motor Vehicles Mfrs. Ass'n v. State Farm Ins. Co.*, 463 U.S. 29, 42, 52, 57 (1983).

This case demonstrates the astonishing results of an agency's failure to take costs and risk trade-offs into account. EPA never considered whether the massive costs associated with its proposals (as much as $150 billion annually) might ironically promote the very conditions that lead to the asthma and other respiratory problems EPA sought to prevent. In fact, EPA deliberately refused to consider such costs due to a misguided 20-year-old-decision of the D.C. Circuit Court of Appeals. *Lead Industries Assns. v. EPA*, 647 F.2d 1130, 1148, 1153-54 (D.C. Cir.) (Wright, C.J.), *cert. denied*, 449 U.S. 1042 (1980). Because the costs of EPA's rules are likely to be passed on to society at large, they can be expected to increase consumer prices and will almost certainly have a disproportionate impact on the poorest segments of the population, which are at the highest risk for asthma and other respiratory diseases.[2] Given the conclusion of the American Thoracic Society that "poverty may be the number one risk factor for asthma," EPA's rules may aggravate the problem they are intended to solve.

Moreover, EPA ignored the likely effect of its ozone rule on skin cancer rates. Due to ozone's beneficial blocking effect on ultraviolet-B (UV-B) radiation, the revised ozone standard will increase malignant and non-melanoma skin cancers and cataracts. An uncontradicted Department of Energy analysis indicates that EPA's ten parts per billion (ppb) change in the ozone standard could result in 25-50 new melanoma-caused fatalities, 130 to 260 incidences of cutaneous melanoma, 2,000 to 11,000 new cases of non-melanoma skin cancer, and 13,000

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[2] *See* Susan E. Dudley, *Economic Impact Analyses*, 16 PACE ENVTL. L. REV. 81, 84 (1998); Susan E. Dudley & Wendy L. Gramm, *EPA's Proposed Ozone Standard May Harm Public Health and Welfare*, 17 INT'L J. OF RISK ANALYSIS 403 (Aug. 1997).

to 28,000 new incidences of cataracts each year. EPA refused to consider this purely health-related trade-off effect of its revised standard.

The text and structure of Section 109 indicate that EPA must consider costs and risk trade-offs in setting National Ambient Air Quality Standards ("NAAQS"). If there were any doubt about the meaning of Section 109, this case would be governed by the principle that reasoned decisionmaking about the regulation of economic activity demands consideration of costs and of risk trade-offs. Under basic precepts of administrative law, agencies are required to conduct a "reasoned analysis" and provide a "reasoned basis" for their decisions. *State Farm*, 463 U.S. at 42, 52, 57. To qualify as "reasoned" under this standard, agency action must consider costs and risk trade-offs. Congress, administrative agencies, and courts have all recognized the importance of considering these factors, and regulatory statutes should be construed with reference to that background principle.

An agency which is *permitted* to consider costs and risk trade-offs is acting arbitrarily unless it *actually does consider* them. Consideration of costs and risk trade-offs is necessary for reasoned decisionmaking in the absence of an express congressional statement precluding an agency from taking those factors into account. "It is only where there is 'clear congressional intent to preclude consideration of cost' that [courts] find agencies barred from considering costs." *Michigan v. EPA*, 2000 U.S. App. LEXIS 3209, *36 (D.C. Cir. Mar. 3, 2000) (citation omitted), *pet. for reh'g and pet. for reh'g en banc denied,* June 22, 2000.

Because there is no clear congressional statement forbidding EPA from considering compliance costs or risk trade-offs in setting NAAQS, EPA is required to consider those factors in order to exercise reasoned decisionmaking under Section 109 of the Clean Air Act.

ARGUMENT

I. REASONED DECISIONMAKING REQUIRES CONSIDERATION OF COSTS AND RISK TRADEOFFS

This Court should articulate a strong presumption that agency action under environmental and other regulatory statutes is unreasonable and contrary to law unless the agency considers (1) costs of compliance (including marginal costs) as well as benefits and (2) risk trade-offs caused by the agency action. This principle follows both from organic regulatory statutes and from the requirements of the Administrative Procedure Act, 5 U.S.C. § 706.[3]

The principle is little more than plain common sense. Two months after the EPA finalized the ozone rule at issue in this case, the Office of Management and Budget reported to Congress that "the only way we know to distinguish between the regulations that do good and those that cause harm is through careful assessment and evaluation of their benefits and costs."[4] Executive orders issued by the Reagan and Clinton Administrations have required agencies to consider costs.[5] Even EPA's Science Advisory Board has documented the dangers of ignoring costs and risk trade-offs.[6] Because allocative choices

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[3] The Clean Air Act itself provides that a reviewing court may reverse any action of the EPA that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Section 307(d)(9)(A), 42 U.S.C. § 7607(d)(9)(A).

[4] Office of Information and Regulatory Affairs, Office of Management and Budget, Report to Congress on the Costs and Benefits of Federal Regulations 10 (1997).

[5] See Exec. Order No. 12,866, 3 C.F.R. 638, 639 (1993), reprinted in 5 U.S.C. 601 (1994); Exec. Order No. 12,291, 3 C.F.R. 127 (1981), revoked by Exec. Order No. 12,866. *See generally* Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 6-7 (1995).

[6] Reducing Risk: Setting Priorities and Strategies for Environmental

made in protecting health and the environment cannot be made in a vacuum, risk management decisions made without regard to associated costs, or without regard to risk trade-offs, are necessarily arbitrary and unreasonable.

As Justice Powell commented in the *Benzene* case, "[t]housands of toxic substances present risks that fairly could be characterized as 'significant.'" *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 670 (1980) (concurring opinion). But "[e]ven if OSHA succeeded in selecting the gravest risks for earliest regulation, a standard-setting process that ignored economic considerations would result in a serious misallocation of resources and *a lower effective level of safety* than could be achieved under standards set with reference to the comparative benefits available at a lower cost." *Id.* (emphasis added). "I would not attribute such an irrational intention to Congress." *Id.*

The need to consider costs and risk trade-offs finds wide support in contemporary studies of the regulatory process.[7] One noted commentator has estimated that a more rational prioritization of regulatory policies could save 60,000 lives, with the expenditure of no additional resources.[8]

Protection, Report of the Science Advisory Board: Relative Risk Reduction Strategies Committee to Administrator, U.S.E.P.A. (Sept. 1990).

[7] *See, e.g.*, Harvard Group on Risk Management Reform, *Reform of Risk Regulation: Achieving More Protection at Less Cost*, 1 HUM & ECOLOGICAL RISK ASSESSMENT 183 (1995); National Academy of Public Administration, Setting Priorities, Getting Results: A New Direction for the U.S. Environmental Protection Agency (1995); President's Council on Sustainable Development, Eco-Efficiency Task Force Report ch 2 (1995) <http://www.whitehouse.gov/WH/EOP/pcsd/tf-reports/eco-top.html>; Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making (1993).

[8] John D. Graham, *Legislative Approaches to Achieving More Protection at Less Cost*, 1997 U. CHI. LEGAL F. 13; *see also* Tammy O. Tengs et al., *Five Hundred Life-Saving Programs and Their Cost-Effectiveness*, 15 RISK ANALYSIS 369 (1995); Tammy O. Tengs & John D. Graham, *The Opportunity Costs of Haphazard Social Investments in Lifesaving*, in Robert

For instance, agency action in the context of CERCLA, the Superfund statute, has often been plagued by a failure to consider costs and risk trade-offs. Cleanup of hazardous waste sites creates increased risk of accidental fatalities, especially in construction and transportation jobs. For a typical site, the accident fatality risk from a cleanup appears to be several times larger than the health risk from not cleaning up.[9] *See generally* John D. Graham & Jonathan B. Wiener, eds., RISK VS. RISK (1995) (documenting many instances where regulatory actions aimed at one risk have spawned even greater countervailing risks).

EPA has often proposed costly Superfund remedies to target trivial risks. In *United States v. Ottati & Goss, Inc.*, 900 F.2d 429, 441 (1st Cir. 1990) (Breyer, J.), the First Circuit affirmed a district court's denial of EPA's proposed remedy for cleaning up soil contaminated with PCBs. EPA sought a remedy that would have reduced PCB concentrations to 20 parts per million ("ppm") rather than 50 ppm, at a marginal cost of $9.3 million. EPA's decision was based on its extraordinary assumptions that (a) developers would build residential housing on the previously undeveloped site, (b) small children, playing in the backyard, would eat dirt containing PCBs, and (c) the children would eat such dirt each day for 245 days per year for three and a half years. *Id.* at 441. The court of appeals opined that "[o]ne might conclude from the cited portions of the record that this amounts to a very high cost for very little extra safety." *Id. See also* Stephen Breyer, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 12 (1993) (spending $9.3 million to protect "non-existent dirt-eating children" is the problem of

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W. Hahn, ed., RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION 167, 172 (Oxford 1996). See also Cass R. Sunstein, *Legislative Foreword: Congress, Constitutional Moments, and the Cost-Benefit State*, 48 STAN. L. REV. 247 (1996).

[9] Alan F. Hoskin, J. Paul Leigh & Thomas W. Planek, *Estimated Risk of Occupational Fatalities Associated With Hazardous Waste Site Remediation*, 14 RISK ANALYSIS 1011 (1994).

"the last 10 percent").

This case demonstrates the dangers of ignoring costs and risk trade-offs. EPA has cited the effects of ozone on asthma and other respiratory diseases, predicting that its rule will reduce "hospital admissions and emergency room visits for respiratory causes, among children and adults with pre-existing respiratory disease such as asthma" and may avoid "possible long-term damage to the lungs." National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856 (1997) (to be codified at 40 C.F.R. pt. 50). Yet even proponents of the EPA rule acknowledge that the vast majority of the population "will observe no effect on their health or well-being as a result of this rule."[10] The President's Council of Economic Advisors has concluded that "reductions in adverse health effects, even for 'sensitive' populations, are small."[11]

With respect to particulate matter, which encompasses a range of different substances of varying sizes and composition, EPA has acknowledged the "uncertainty in the characterization of health effects attributable exposure of ambient PM."[12] The National Academy of Sciences warned that "at the present time, there is uncertainty as to what specific types or components of particulate matter need to be reduced to achieve substantial health-risk reduction cost effectively" and that "[p]roceeding in the absence of such information could leave policymakers to focus on standards and controls for particulate matter that are not of the highest public health priority."[13] In appropriating funds for further PM research, Congress has stated in conference

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[10] Dudley, *supra* note 2, at 84.

[11] *Id.* (quoting comments).

[12] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,655 (1997) (to be codified at 40 C.F.R. pt. 50).

[13] Board of Environmental Studies and Toxicology, National Research Council, RESEARCH PRIORITIES FOR AIRBORNE PARTICULATE MATTER: I. IMMEDIATE PRIORITIES AND A LONG-RANGE RESEARCH PORTFOLIO 10, 15 (1998).

reports that "at present, there appears to be insufficient data available for the Agency to decide what changes, if any, should be made to the current standard"[14] and that "sufficient facts are not yet available to proceed with future regulations for a new particulate standard."[15] After EPA issued the revised PM standard, Congress postponed implementation until monitors were put in place and three years' worth of data were gathered.[16] Congress also postponed implementation of the ozone standard by one year.[17]

Both Congress and EPA have thus recognized that the benefits claimed by the agency are speculative. Weighing against these tenuous benefits are substantial costs. According to the EPA's analysis, full implementation of the ozone standard will impose direct annual costs of $ 9.6 billion, with monetized health and welfare benefits ranging from $ 1.5 to $ 8.5 billion.[18] Hence, EPA acknowledged that the costs of the ozone standard will exceed its expected benefits. Implementation of both the ozone and the particulate standards will cost, according to EPA, close to $47 billion annually[19] – more than the Nation currently

[14] H.R. Rep. No. 104-812, at 70 (1996).

[15] H.R. Rep. No. 105-297, at 115 (1997).

[16] Pub. L. No. 105-178, §§ 6101-03, 112 Stat. 465 (1998).

[17] Pub. L. No. 105-178, § 6103(a), 112 Stat. 465 (1998).

[18] See National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38,856 (1997) (to be codified at 40 C.F.R. pt. 50); National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652 (1997) (to be codified at 40 C.F.R. pt. 50); Revised Requirements for Designation of Reference and Equivalent Methods for PM and Ambient Air Quality Surveillance for Particulate Matter, 62 Fed. Reg. 38,764 (1997) (to be codified at 40 C.F.R. pts. 53 and 58); Innovative Strategies and Economics Group, EPA, Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule 13-2 (1997).

[19] Innovative Strategies and Economics Group, *supra* note 18, at 13-2.

spends for all Clean Air Act programs combined.[20]

There are substantial indirect costs as well. EPA believes that, even by the year 2010, a large part of the country will not be able to meet the new standards and thus will face penalty provisions under the law that will slow economic growth.[21] One analyst calculates some $80 billion in hidden costs stemming from the penalty provisions triggered by such inability to comply.[22] Another analyst puts the total cost at $150 billion.[23]

The very magnitude of these costs makes it unthinkable that Congress intended EPA to disregard them. *Cf. FDA v. Brown & Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1301 (2000) ("[W]e must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency."). Moreover, EPA has made no effort to justify the tremendous costs associated with its proposal. This failure is significant because regulatory costs have substantial negative impacts on public health. As one federal court has cautioned, "[h]igher income is associated with better nutrition and medical care; regulations creating costs exceeding $ 7.5 million per life (directly) saved may well yield greater indirect loss of life." *Monsanto Co. v. EPA.*, 19 F.3d 1201, 1210 (7th Cir. 1994); *see also International Union, UAW v. OSHA*, 938 F.2d 1310, 1326 (D.C. Cir. 1991) (Williams, J., concurring) (explaining that recent studies predict that "each $7.5 million of costs generated

[20] See Office of Air and Radiation, EPA, The Benefits and Costs of the Clean Air Act: 1970 to 1990, at ES-2 (1997).

[21] EPA estimates that between thirty-nine and fifty-seven million people will live in areas that cannot attain the old standard, and an additional fourteen to thirty-two million people will live in areas that are out of compliance with the new standard. See National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. at 38,856.

[22] Dudley, *supra* note 2, at 83.

[23] Anne E. Smith, *et al.*, *Costs, Economic Impacts, and Benefits of EPA's Ozone & Particulate Standards* 9 (1997), OJA 3323.

by regulation may . . . induce one premature fatality" in the public through reduced availability of resources for medical care and safety).

EPA's revised standards will impose massive costs on economically productive activities – increasing consumer prices, reducing employment, and decreasing incomes and living standards. These effects will be felt most acutely by the poor and other segments of the population at highest risk for the health problems targeted by EPA. Asthma is overrepresented among the urban poor and has increased in recent years despite overall improvements in air quality (ground ozone levels in particular declined six percent between 1986 and 1995).[24] A report by the National Institute of Allergy and Infectious Diseases concluded that "the leading cause of asthma by far was . . . proteins in the droppings and carcasses of the German cockroach."[25] The American Thoracic Society has offered that "poverty may be the number one risk factor for asthma."[26]

The substantial costs imposed by EPA's rules could ironically promote the very conditions that lead to asthma and other respiratory problems. Yet EPA never even considered the possibility that its "cure" could be worse than the disease.

Moreover, EPA ignored the likely effect of its ozone rule on skin cancer rates.[27] Due to ozone's beneficial blocking effect on ultraviolet-B (UV-B) radiation, the revised ozone standard will increase malignant and non-melanoma skin cancers and cataracts. The protective effect of ozone is well documented and forms the basis for EPA's own stratospheric ozone rules.[28] Tropospheric ozone is, if anything, more effective than

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[24] EPA, Office of Air Quality, Nat'l Air Quality and Emission Trends Rep. (1995).

[25] Quoted in Dudley, *supra* note 2, at 84.

[26] *Id.* at 84-85.

[27] *See* Dudley & Gramm, *supra* note 2.

[28] 42 U.S.C. § 7671.

stratospheric ozone at blocking UV-B radiation.[29] EPA has acknowledged that its ozone rule will have a deleterious impact on UV-B related health problems.[30] An uncontradicted Department of Energy analysis indicates that the ten parts per billion (ppb) change in the ozone standard could result in 25-50 new melanoma-caused fatalities, 130 to 260 incidences of cutaneous melanoma, 2,000 to 11,000 new cases of non-melanoma skin cancer, and 13,000 to 28,000 new incidences of cataracts each year.[31] A peer-reviewed scientific paper by two Office of Management and Budget staff members reached a similar conclusion.[32]

Rather than addressing these important tradeoffs, EPA declined to consider them in promulgating its new ozone standard. And it declined to consider the possible existence of other, cheaper means to achieve its objectives. Such decisionmaking is arbitrary and unreasonable. The risks of such a process are illustrated by the tragic decision by Peru to suspend chlorination of its drinking water in the wake of U.S. risk

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[29] Paul J. Crutzen, *Ultraviolet on the Increase*, 356 NATURE 104 (1992) ("Ozone in the troposphere, an industrial pollutant, is (molecule for molecule) a stronger absorber of ultraviolet than ozone in the stratosphere"); *see generally* Ignacio Galindo *et al.*, *Ultraviolet Irradiance over Mexico City*, 45 AIR & WASTE MGMT. ASS'N 886 (1995); National Research Council, Rethinking the Ozone Problem in Urban and Regional Air Pollution 110 (1991); G. Seckmeyer & R.L. McKenzie, *Increased Ultraviolet Radiation in New Zealand (45 [degrees] S) Relative to Germany (48 [degrees] N)*, 359 NATURE 135 (1992); John E. Frederick *et al.*, *Empirical Studies of Tropospheric Transmission in the Ultraviolet: Broadband Measurements*, 32 J. APPLIED METEOROLOGY 1883 (1993).

[30] EPA, *Calculations of the Impact of Tropospheric Ozone Changes on UV-B Flux and Potential Skin Cancers* (Draft) (Sept. 1994) (Ozone JA 3089-3104).

[31] Statement of Marvin Frazier, DOE Office of Health & Environmental Research Before CASAC (Mar. 21, 1995), Ozone JA 258-59.

[32] Randall Lutter & Christopher Wolz, *UV-B Screening by Tropospheric Ozone: Implications for the National Ambient Air Quality Standard*, 31 ENVTL. SCI. & TECH. 142A (1997).

assessments classifying the chlorination process as carcinogenic. This decision led to the largest outbreak of cholera in recent times, in which over 800,000 people became ill and nearly 7,000 died.[33]

II. THE CLEAN AIR ACT AND WELL-ESTABLISHED LEGAL PRINCIPLES MANDATE CONSIDERATION OF COSTS AND RISK TRADE-OFFS

EPA's refusal to consider costs and risk trade-offs in the ozone and particulate matter rulemakings is thus the hallmark of arbitrary and capricious decisionmaking. EPA's action should be held violative both of the Clean Air Act and of familiar principles of administrative law. Acts of Congress empowering agencies to regulate economic activity should be construed in light of the fact that reasoned decisionmaking about these matters requires consideration of costs and of risk trade-offs.

A. The Clean Air Act Compels Consideration of Costs and Risk Trade-Offs

Two sections of the Act govern the establishment, review, and revision of National Ambient Air Quality Standards ("NAAQS"). Section 108 (42 U.S.C. § 7408) directs EPA to identify certain pollutants which "may reasonably be anticipated to endanger public health or welfare" and to issue air quality criteria for them. These air quality criteria are to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air . . . ."

Section 109 (42 U.S.C. § 7409) directs EPA to propose and

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[33] Christopher Anderson, *Cholera Epidemic Tied to Risk Miscalculation*, 354 NATURE 255 (Nov. 28, 1991).

promulgate "primary" and "secondary" NAAQS for pollutants identified under Section 108. Those standards may then be reviewed and revised as "appropriate." Section 109(d)(1). Section 109(b)(1) defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria and allowing an adequate margin of safety, are requisite to protect the public health." A secondary standard, as defined in section 109(b)(2), must "specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on [the] criteria, [are] requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."

1. EPA must consider costs and risk trade-offs in using "judgment" to provide "an adequate margin of safety."

The statute certainly does not *direct* EPA to reduce health risks without regard to cost or risk trade-offs. Rather, on its face Section 109(b)(1) directs the EPA Administrator to use her "judgment" in providing "an adequate margin of safety . . . to protect the public health." In order to make a reasoned "*judgment*," EPA is surely bound to consider costs and risk trade-offs. In deciding whether a revised standard is "*appropriate*" under Section 109(d)(1), EPA must consider the same factors.

Further, in deciding whether a "margin of safety" is "*adequate*" under Section 109(b)(1), EPA must address cost and risk trade-offs – just as an agency must consider the same factors in deciding whether a certain margin of safety is "*ample*" or whether a particular health risk is "*significant*." A margin of safety is not "adequate" if it entails excessive costs or risks. Just as one is entitled to ask, "Can an agency sensibly decide whether a risk is 'significant' without also examining the cost of eliminating it?", Stephen G. Breyer, Richard B. Stewart, Cass R. Sunstein & Matthew L. Spitzer, ADMINISTRATIVE LAW AND REGULATORY POLICY 65 (4th ed. 1999), one is also entitled to ask, "Can an agency sensibly exercise 'judgment' in deciding whether a 'margin of safety' is 'adequate' without considering

cost?"

Thus, in *Michigan v. EPA*, 2000 U.S. App. LEXIS 3209, *34-35 (D.C. Cir. Mar. 3, 2000), *pet. for reh'g and pet. for reh'g en banc denied,* June 22, 2000, the D.C. Circuit held that determining whether emissions "contribute significantly" to the nonattainment of pollution standards entailed consideration of costs. The D.C. Circuit held that cost is relevant where a statutory "mandate directed to some environmental benefit is phrased in general quantitative terms ('ample margin of safety,' 'substantial restoration,' and 'major')," even where the text "contains not a word alluding to non-health trade-offs." *Id.* at *36.

And in *Natural Resources Defense Council v. EPA*, 824 F.2d 1146, 1163 (D.C. Cir. 1987) (en banc), the court of appeals held that costs were relevant to determining whether an air quality standard for hazardous pollutants under § 112 of the Clean Air Act offered an "ample margin of safety" to protect the public health.

Section 109 is structured in similarly "general quantitative terms," *Michigan v. EPA*, 2000 U.S. App. LEXIS 3209, at *36, using precisely the sort of terminology ("judgment," "appropriate," "adequate margin of safety") that by its nature requires consideration of cost and risk trade-offs.

2. EPA must consider costs and risk trade-offs in protecting the "public health" under Section 109.

Section 109(b) directs EPA to protect the "public health" rather than the health of any particular person. By contrast, other provisions of the Clean Air Act direct EPA to focus on certain specific subpopulations – such as particularly susceptible individuals or those most exposed to a pollutant.[34] The distinction is important. "Public health" is a multi-dimensional concept referring to a variety of factors relating to mortality, morbidity, and life expectancy. Promoting the "public health"

[34] Section 108(f)(1)(C), 42 U.S.C. § 7408(f)(1)(C); Section 112(c)(9)(B)(i), 42 U.S.C. § 7412(c)(9)(B)(i); Section 112(f)(2)(A), 42 U.S.C. § 7412(f)(2)(A).

entails managing risks in a comprehensive way.

"Public health" efforts are "directed toward sanitation of the environment, control of communicable infections, . . . and *the development of social machinery to ensure for every individual a standard of living adequate for the maintenance of health.*" 9 ENCYCLOPEDIA BRITANNICA: MICROPEDIA 778 (15th ed. 1992) (emphasis added). A leading public health official and cancer specialist in the United Kingdom described "improvements in nutrition, housing, water supplies, and sewage" as "fairly simple improvements in public health." John Cairns, CANCER: SCIENCE AND SOCIETY 8 (1978).

As Justice Powell recognized in *Union Electric Co. v. EPA*, 427 U.S. 246 (1976), the "shutdown of an urban area's electrical service could have an even more serious impact on the health of the public than that created by a decline in ambient air quality." *Id.* at 272 (concurring opinion). A House report accompanying the 1977 Clean Air Amendments explained that "a healthful environment, energy conservation, and a sound economy are interrelated factors bearing on the quality of life of the Nation." H.R. Rep. No. 95-294, at 61 (1977). Precisely because of the dangers of ignoring costs and risk trade-offs, public health scholars have urged "a more holistic paradigm [in] which decisionmakers would 'treat the whole patient' instead of confining their thinking to bounded fragments of larger systems." Graham & Wiener, RISK VS. RISK, at 227.

By directing EPA to promote the "public health," Congress instructed the agency to take a broad view that necessarily includes consideration of costs and risk trade-offs.

3. Section 108 confirms that EPA must consider costs and risk trade-offs.

Section 109 must be read in conjunction with Section 108, which sets out the criteria by which EPA is to identify pollutants for which NAAQS must be set. Section 108(a)(2) directs EPA to consider public "welfare" as well as "public health" and to consider "any known or anticipated adverse effects on welfare," not just impacts on health. Welfare effects as defined in section 302(h) (42 U.S.C. § 7602(h)) include, but are not limited to,

"effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, *as well as effects on economic values and on personal comfort and well-being*." (emphasis added).

Accordingly, from the very beginning of the process by which NAAQS are established, EPA is instructed to consider costs and risk trade-offs in the form of "effects on economic values and on personal comfort and well-being." Indeed, Section 108(a)(2) directs EPA to consider "the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare." 42 U.S.C. § 7408(a)(2).

4. The structure of the statute likewise confirms that EPA must consider costs and risk trade-offs.

Section 109(d)(2) of the Clean Air Act requires appointment of an independent scientific review committee to review criteria and standards and recommend new standards or revisions of existing criteria and standards, as appropriate. The committee established under section 109(d)(2) is known as the Clean Air Scientific Advisory Committee (CASAC), a standing committee of EPA's Science Advisory Board. Section 109(d)(2)(C) requires the CASAC to "advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." 42 U.S.C. § 7409(d)(2)(C).

Thus, Congress required, in the statutory section governing adoption of NAAQS, that the EPA Administrator be advised on the "economic" and "social" effects of such standards. Such a mandate would be odd indeed if the Administrator were precluded from considering such factors in adopting NAAQS.

In addition, before commencing a NAAQS rulemaking, EPA must issue information on costs. Section 108(b)(1), 42 U.S.C. § 7408(b)(1). The only possible purpose of such a requirement is to enable commenters to critique EPA's cost assessment in the NAAQS rulemaking proceeding.

5. In practice, it is impossible to set NAAQS by reference to health alone.

In practical fact, NAAQS under the Clean Air Act are often set with regard to non-health factors, whether explicitly or not. Neither science nor health considerations alone can definitively determine whether to set a given standard at one level rather than another. For example, in this case, EPA's science advisors concluded that there was no basis for determining a specific threshold level of ozone that would assure protection of public health and welfare. EPA's own scientific experts did not view the agency's decision as purely a health issue, and they did not find the proposed standard to be significantly more protective of public health than the existing standard.[35]

Moreover, the impossibility of excluding factors like costs is underscored by the fact that there is a continuum of health effects associated with many pollutants. EPA has conceded, for instance, that there is no threshold level for ozone below which no adverse health effects would be expected to occur.[36] Given the absence of any threshold, consideration of health effects alone logically would lead EPA to setting a standard of zero for ambient pollutant concentrations. For zero is the only level at which there can be assurance of no adverse health effects. Yet EPA has long acknowledged that Congress never intended such an absurd result.

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[35] The CASAC stated "that there is no 'bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health" and that "the selection of a specific level and number of allowable exceedances is a policy judgment." 62 Fed. Reg. at 38,862. The CASAC observed that "the differences in the percent of outdoor children . . . responding between the present standard and the most stringent proposal . . . are small and their ranges overlap for all health endpoints." *Id.*

[36] See Final Rule, 62 Fed. Reg. at 38,863 ("[I]n the absence of any discernable threshold, it is not possible to select a level below which absolutely no effects are likely to occur. Nor does it seem possible, in the Administrator's judgment, to identify a level at which it can be concluded with confidence that no 'adverse' effects are likely to occur.").

Instead of admitting to explicit consideration of costs and risk trade-offs, EPA purported to set the ozone standard based solely on "public health policy judgments in addition to determinations of a strictly scientific nature." Final Rule, 62 Fed. Reg. at 38,863 (citation omitted). EPA insisted that, because its decision was "largely judgmental in nature," it "may not be amenable to quantification in terms of what risk is 'acceptable' or any other metric." *Id.* at 38,883.

The invocation of the vague "policy judgments" label simply masks the exercise of the agency's discretion and ensures that its decisions are neither publicly accountable nor subject to meaningful judicial review. Rather than supporting EPA's construction of the statute, EPA's defense demonstrates that the agency operates by pragmatically considering factors such as costs – but in an unreviewable, back-door fashion.

B. The Applicable "Clear Statement" Rule Requires Consideration of Costs and Risk Trade-Offs

If the text and structure of the Clean Air Act left any doubt, this case would be governed by the principle that, in order to engage in reasoned decisionmaking, a federal agency is *required* to consider costs and risk trade-offs in the absence of an express congressional statement *forbidding* the agency from doing so. An agency which is *permitted* to consider costs and risk trade-offs is acting arbitrarily unless it *actually does consider* them. The agency must also give a reasoned explanation of how it considered those factors.[37]

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[37] It does not follow, of course, that it would necessarily be irrational to the point of unconstitutionality for Congress itself to withhold cost-weighing authority from a given agency in a particular setting, having perhaps considered costs itself or assigned that task to another agency with coordinate jurisdiction. The principle we urge upon the Court is the more modest one that, *unless* Congress has clearly excluded consideration of costs from a given agency's decisionmaking process, such consideration must be deemed to fall within that agency's authority, and the agency's refusal in *those* circumstances to take costs into account is arbitrary and capricious, in violation of the APA and the agency's own organic statute.

The test for finding that Congress has prohibited consideration of costs and risk trade-offs is stringent: "It is only where there is 'clear congressional intent to preclude consideration of cost' that [courts] find agencies barred from considering costs." *Michigan v. EPA*, 2000 U.S. App. LEXIS 3209, *36 (D.C. Cir. Mar. 3, 2000) (citation omitted).

Thus, in *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 655 (1980), a plurality of this Court refused to find that the phrase "significant risk" in § 3(8) of the Occupational Health and Safety Act, 29 U.S.C. § 652(8), precluded consideration of cost. The plurality understood a "significant" risk as something more than a "mathematical straitjacket" and held that "some risks are plainly acceptable and others are plainly unacceptable." *Id.* at 655 (plurality opinion). The plurality withheld judgment on whether the Act required a "reasonable correlation between costs and benefits," *id.* at 615, but OSHA has since interpreted § 3(8) and regulation of "significant risk" to require "cost-effective protective measures" and has set standards with an eye toward "the costs of safety standards [being] reasonably related to their benefits." *See International Union v. OSHA*, 37 F.3d 665, 668-69 (D.C. Cir. 1994) (quoting OSHA's final rule).

In *George E. Warren Corp. v. EPA*, 159 F.3d 616, 622-24 (D.C. Cir. 1998), *reh'g granted*, 164 F.3d 676 (D.C. Cir. 1999), the D.C. Circuit interpreted the statutory scheme for the reformulated gasoline program, which had the "overall goal" of improving air quality and "reducing air pollution." *Id.* at 622. Even though the relevant statutory provision contained no reference to cost, the court held that the effect of a proposed rule on the price and supply of gasoline were relevant factors for EPA to consider. *Id.* at 623.

In *Grand Canyon Air Tour Coalition v. FAA*, 154 F.3d 455, 475 (D.C. Cir. 1998), *cert. denied*, 119 S. Ct. 2046 (1999), the statute required the FAA to devise a plan for "substantial

restoration of the natural quiet" in the Grand Canyon area. The D.C. Circuit found that the statute did not preclude the FAA's consideration of costs to the air tourism industry in deciding how "substantial" that restoration must be. *See also Irving v. United States*, 162 F.3d 154, 168 n.13 (1st Cir. 1998), *cert. denied*, 120 S. Ct. 47 (1999) ("[Plaintiff] espouses the logic of zero tolerance for any kind of risk. The indiscriminate application of this logic as a guide for policy has met with considerable criticism.. See, e.g., Stephen Breyer, BREAKING THE VICIOUS CIRCLE 11-19 (1993). . . . [C]ourts must be hesitant to impose such a gloss in the absence of an explicit congressional command or proper grant of agency discretion."); Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 HARV. L. REV. 405, 487 (1989) (suggesting an "interpretive principle" drawn from case law that reviewing courts will read statutes as authorizing regulations with benefits at least "roughly commensurate with their costs, unless there is a clear legislative statement to the contrary").

The Clean Air Act does not contain the requisite clear statement prohibiting EPA from considering costs with respect to the establishment of NAAQS. Indeed, Section 101(b) of the Clean Air Act states that the purpose of the Act is "to protect and enhance the quality of the Nation's air resources *so as to promote* the *public health* and *welfare* and the *productive capacity* of its population." 42 U.S.C. § 7401 (emphasis added). The 1990 Amendments included a provision requiring EPA, in consultation with other executive departments, to "conduct a comprehensive analysis of the impact of [the Clean Air] Act on the public health, economy, and environment of the United States." 42 U.S.C. § 7612(a). EPA was directed to "consider the costs, benefits and other effects associated with compliance" with the various provisions in the Act, specifically including the NAAQS. *Id.* Thus, Congress spoke to the requirement to consider costs and benefits in the Act, and EPA was remiss in not doing so.

Section 109 should also be interpreted with reference to the overriding principle that reasoned decisionmaking requires

agency consideration of costs and risk trade-offs – a principle that Congress has repeatedly recognized since the New Deal. Flood Control Act of 1936, ch. 688, 1, 49 Stat. 1570, 1570 (codified as amended at 33 U.S.C. § 701a), for example, directs that projects should be approved if "the benefits to whomsoever they may accrue are in excess of the estimated costs."

Consideration of cost permeates environmental statutes, demonstrating Congress' recognition of the importance of taking economic factors into account. For example, the Toxic Substances Control Act[38] and the Federal Insecticide, Fungicide and Rodenticide Act[39] require EPA to balance costs and benefits in regulating chemicals and pesticides. In the Safe Drinking Water Act Amendments of 1996,[40] Congress required comprehensive risk analysis as well as independent peer review of the scientific bases for EPA action. In the Accountable Pipeline Safety and Partnership Act of 1996,[41] Congress mandated risk management and peer review. In reforming the Delaney Clause, Congress moved away from a zero risk policy regarding food additives.[42]

In addition to these specific statutes, Congress has also generically mandated the systematic consideration of cost and risk trade-offs. For example, the Small Business Regulatory Enforcement Fairness Act of 1996[43] requires EPA to consider and minimize the impacts of its rules on small businesses.

During the enactment of the Consumer Products Safety Act,

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[38] 15 U.S.C. § 2605(c)(1).

[39] 7 U.S.C. § 136(bb).

[40] Pub. L. No. 104-182, 110 Stat. 1613, codified at 42 U.S.C. § 300f et seq (1994 & Supp 1996).

[41] Pub. L. 104-304, 110 Stat. 3793 (1996), codified at 49 U.S.C. § 60101 et seq (1994 & Supp 1996).

[42] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, 1514-35, codified at 21 U.S.C. § 346a (1994 & Supp 1996).

[43] Pub. L. No. 104-121, 110 Stat. 857-874 (1996) (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C. and 28 U.S.C.).

House and Senate reports summarized the pattern of congressional action:

> Protection against unreasonable risks is central to many Federal and State safety statutes and the courts have had broad experience in interpreting the term's meaning and application. It is generally expected that the determination of unreasonable hazard will involve the Commission in balancing the probability that risk will result in harm and the gravity of such harm against the effect on the product's utility, cost, and availability to the consumer.

H. R. Rep. No. 92-1153, at 33 (1972); S. Rep. No. 92-749, at 14-15 (1972).

EPA's anomalous construction of Section 109 is out of step with Congress' repeated recognition of the importance of considering costs and risk trade-offs.

C. Administrative Law Principles Require Consideration of Costs and Risk Trade-Offs

The judicial branch is similarly familiar with the need to consider costs and risk trade-offs. The standard of "reasonableness" in tort law requires a court to consider the costs of safety precautions as well as their expected benefits. *See United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (Hand, J.). The common-law doctrine of "nuisance" also entails a balancing inquiry and a consideration of cost. *See* Restatement (Second) of Torts §§ 826-28.

This Court has held that, under principles of administrative law, agencies must conduct a "reasoned analysis" and furnish a "reasoned basis" for their decisions. *Motor Vehicles Mfrs. Ass'n v. State Farm Ins. Co.*, 463 U.S. 29, 42, 52, 57 (1983). Numerous decisions have recognized that, to qualify as "reasoned" under this standard, agency action must consider costs and risk trade-offs. In *Corrosion Proof Fittings v. EPA*,

947 F.2d 1201, 1214-15 (5th Cir. 1991), for example, the court of appeals held that EPA, under the Toxic Substances Control Act, could not ban of the use of asbestos in brake linings without considering countervailing risks. The court explained that EPA sought to ban asbestos as a carcinogen, but had considered neither the carcinogenicity of likely substitutes, nor whether traffic accidents might be increased due to reduced brake efficiency. The court held that EPA's refusal to consider the risk of substitutes "deprives its order of a reasonable basis" because "EPA cannot say with any assurance that its regulation will increase workplace safety when it refuses to evaluate the harm that will result from the increased use of substitute products." "[E]ager to douse the dangers of asbestos, the agency inadvertently actually may increase the risk of injury Americans face." *Id.*

Similarly, in *Competitive Enterprise Institute v. NHTSA*, 956 F.2d 321 (D.C. Cir. 1992), the D.C. Circuit held that the National Highway Traffic Safety Administration's automobile fuel efficiency rulemaking was not "reasoned" when the agency focused on the environmental risks of excessive fuel use but failed to consider the countervailing risks posed by smaller and less crash-worthy vehicles. Observing that an agency must supply a "reasoned analysis" for its decision, the court of appeals held that NHTSA had failed to confront the requisite trade-off. The defect was "not . . . NHTSA's judgment call, but . . . NHTSA's attempt to paper over the need to make a call." *Id.* at 323.

Courts construing regulatory statutes have recognized the need for agencies to consider costs and risk trade-offs. In *American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U.S. 490 (1981), this Court refused to interpret the Occupational Health and Safety Act as requiring absolute safety. To the contrary, this Court recognized that "Congress was concerned that the Act might be thought to require achievement of absolute safety, an impossible standard, and therefore insisted that health and safety goals be capable of economic and technological accomplishment." *Id.* at 514. In upholding the OSHA cotton

dust standard, this Court noted that "OSHA presented a 'responsible prediction' of what its Standard would cost and its impact on 'production, employment, competition, and prices.'" *Id.* at 531.

Subsequently, the D.C. Circuit upheld an interpretation of another provision of the OSH Act as entailing explicit cost-benefit analysis: "Cost-benefit analysis requires identifying values for lost years of human life and for suffering and other losses from non-fatal injuries. . . . Thus, cost-benefit analysis entails only a systematic weighing of pros and cons, or what Benjamin Franklin referred to as a 'moral or prudential algebra.'" *United Auto Workers v. OSHA*, 938 F.2d 1310, 1320-21 (D.C. Cir. 1991).

In *Forester v. Consumer Product Safety Commission*, 559 F.2d 774 (D.C. Cir. 1977), the court of appeals defined "unreasonable risk" in the Federal Hazardous Substances Act, 15 U.S.C. § 1261(s), as involving "a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Id.* at 789; *see also Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Comm'n*, 569 F.2d 831, 844 (5th Cir. 1978) (vacating agency action because "the Commission has a duty to take a hard look, not only at the nature and severity of the risk, but also at the potential the standard has for reducing the severity or frequency of the injury, and the effect the standard would have on the utility, cost or availability of the product").

In *Consolidated Rail Corp. v. ICC*, 646 F.2d 642 (D.C. Cir. 1981), the court of appeals reviewed an Interstate Commerce Commission adjudication of shippers' claims that a rate based on the expense of certain safety precautions was not "reasonable," because the precautions themselves were excessive. The court explained that the ICC was bound to consider costs in setting safety rules:

> The safety measures for which expenditures are made must be reasonable ones, which means first, that they produce an expected safety benefit commensurate to their cost; and second, that when compared with other possible safety measures, they represent an economical means of achieving the expected safety benefit.

Id. at 648.

EPA's action in this case should be held invalid under both the Clean Air Act and the APA. Decisionmaking that ignores costs and risk tradeoffs should be held violative of the underlying regulatory statute and should also be deemed "arbitrary and capricious" under the APA, 5 U.S.C. § 706.

CONCLUSION

The decision of the Court of Appeals should be reversed to the extent it held that EPA was not required to consider (and in fact was precluded from considering) non-health factors, including the costs of compliance and risk trade-offs. The case should be remanded for application of a proper construction of the Clean Air Act.

Respectfully submitted,

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